FDA/CDER Enterprise Architecture Technical Reference Model

Version: 1.0

January 16, 2004

Table of Contents

1 EXECUTIVE SUMMARY

The CDER Technical Reference Model (C-TRM) defines a taxonomy of services for classifying CDER EA technology standards (as described separately in the "CDER Technology Standards Profile") as well as current technologies in use by CDER systems.

The taxonomy consists of ten service areas: User Services, Application Services, Programming Services, Data Management, Data Interchange, Network Services, Operating Systems, Hardware Platform, Security (Crosscutting), and Systems Management (Crosscutting). Each of the service areas is further divided into multiple service categories. The definitions of the service areas and service categories are geared toward supporting the layers and communication channels of a tiered information system.

The C-TRM serves to classify EA standards for software, hardware, and technology specifications for use within the Center. A key focus of the C-TRM and the Technology Standards Profile is to establish and promote the use of preferred choices for reusable software and hardware components that are founded on industry standards and known to interoperate successfully. The C-TRM provides a framework for classifying organizational areas of expertise and IT development needs, and for targeting areas for enterprise architecture definition and improvement.

The C-TRM is founded on and subordinate to the FDA Technical Reference Model.

2 INTRODUCTION

This section defines the concept of a technical reference model and where it fits in the context of CDER EA.

2.1 PURPOSE

The purpose of this document is to describe the elements of the Technical Reference Model for the Center for Drug Evaluation and Research Enterprise Architecture (CDER EA).

2.2 SCOPE

The CDER Technical Reference Model is a component of the CDER Enterprise Architecture, which itself is a component of the FDA Enterprise Architecture. The C-TRM defines a taxonomy

of services that enables effective IT standards selection and acquisition. This taxonomy categorizes technologies in use throughout the Center. The CDER Technology Standards Profile provides the list of EA standards and technologies in use and recommended by the Center and FDA.

The C-TRM is founded on and subordinate to the FDA Technical Reference Model.

2.3 HOW TO USE THIS DOCUMENT

This document is to be used in conjunction with the FDA and CDER Technology Standards Profiles.

- Use this document to identify the service areas and categories that address a business need (e.g., user services) or project development requirements (e.g., programming services, data management). Service areas and categories are defined in Section 4.
- Once identified, cross-reference these service area/category combinations with the CDER Technology Standards Profile to find recommended tools and standards.
- If the defined service areas and categories do not fully address the requirement, contact the CDER Enterprise Architecture Team for help in identifying recommended tools and standards.
- If the recommended tools do not fully address the need, or if a specific non-standard tool must be used, a waiver must be filed with the agency EA team. Contact the CDER Enterprise Architecture Team for further guidance and support in addressing the issue.

The CDER Enterprise Architecture Team may be reached at CDER-EA@cder.fda.gov.

2.4 REVISION SCHEDULE

This Technical Reference Model and the associated CDER Technology Standards Profile shall be reviewed and updated quarterly unless changes in business or technology direction requires otherwise.

2.5 RELATED DOCUMENTS

This section references documents used as the basis for developing the C-TRM as well as related documents to be used in conjunction.

"FDA Enterprise Architecture Technical Reference Model, Version 1.1", prepared by Blueprint Technologies, March, 2003 .

"Current CDER Technology Standards", prepared by Janet Gentry, Enterprise Architect, CDER OIT

3 SERVICE AREAS

This section introduces the ten service areas of the C-TRM.

The following diagram depicts the overall structure of the C-TRM. At this level of detail, the C-TRM is identical to the FDA and DHHS TRMs. The following section is excerpted from the FDA Technical Reference Model, version 1.1.

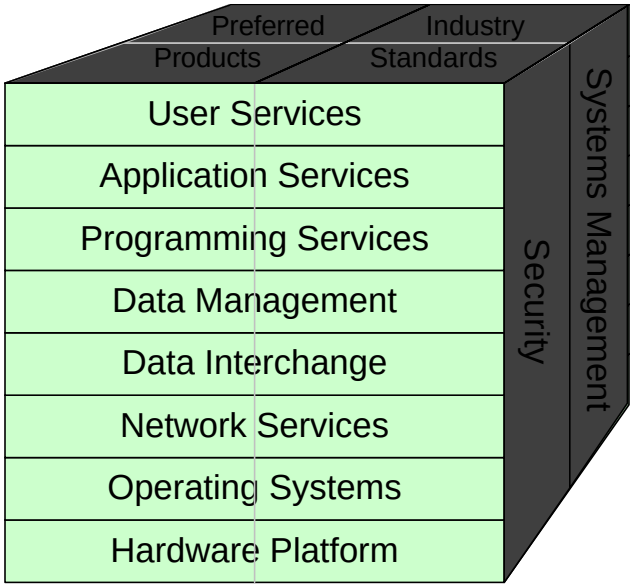

Figure 1. The DHHS Technical Reference Model

The DHHS Technical Reference Model is composed of ten service areas. These come directly from the DHHS TRM and are in use by other federal departments as well.

- **User Services** – Methods by which people can interact with an application both to view outputs and make inputs.
- **Application Services** – Whole applications and significant components for creating, manipulating, and transforming information into useful forms.
- **Programming Services** – Design-time tools for developing and maintaining software that exhibits desired characteristics; software engineering methodologies and tools.
- **Data Management** – Data dictionaries, database management systems, document management systems, and data warehouses.
- **Data Interchange** – Specialized support for the exchange of information, formats, and semantics of data entities among applications on the same or different platforms.
- **Network Services** – Low level capabilities and mechanisms needed to support distributed communications between platforms, applications, and users.

- **Operating Systems** – Software environments and base interfaces within all computing devices that manage hardware resources and make them available to software applications.
- **Hardware Platform** – The physical layer and the infrastructure necessary to support the other services.
- **Security (Crosscutting)** – Products that secure distribution and integrity of data and information and protect the computing infrastructure from unauthorized access at all levels.
- **Systems Management (Crosscutting)** – Mechanisms to monitor and control the operation of individual applications, databases, systems, platforms, networks, and user interactions with these components at all levels.

The last two service areas are "crosscutting", meaning they overlap with the other eight service areas. These services areas comprise the second dimension of the cube depicted in Figure 1.

The third dimension of the TRM is technology type. Technologies are

- **Preferred Products** – Purchased software applications, components, tools, systems, or hardware platforms that are preferred choices in a given category.
- **Industry Standards** – Product-independent specifications for how a technology is to be implemented – written and promoted by government entities, professional societies, or trade associations.

3.1 SERVICE AREAS BY LOGICAL TIER

The C-TRM follows the FDA method of classifying service areas. Because the purpose of the TRM is to support CDER and FDA enterprise architecture and because most FDA information systems have a tiered architecture, the FDA TRM maps to the logical tiers of a typical information system as its primary perspective for classification decisions. The following discussion on service area mapping is excerpted directly from the FDA Technical Reference Model.

Figure 2 maps the eight core service areas of the TRM to the typical logical tiers of a modern information system. Information flows into the enterprise through transactional applications and out through reporting applications. (These may be one and the same). Five key service areas then correspond directly to the architectural layers (logical tiers) of this diagram.

Layered Service Areas:

- User Services
- Application Services
- Data Management Services
- Operating Systems
- Hardware

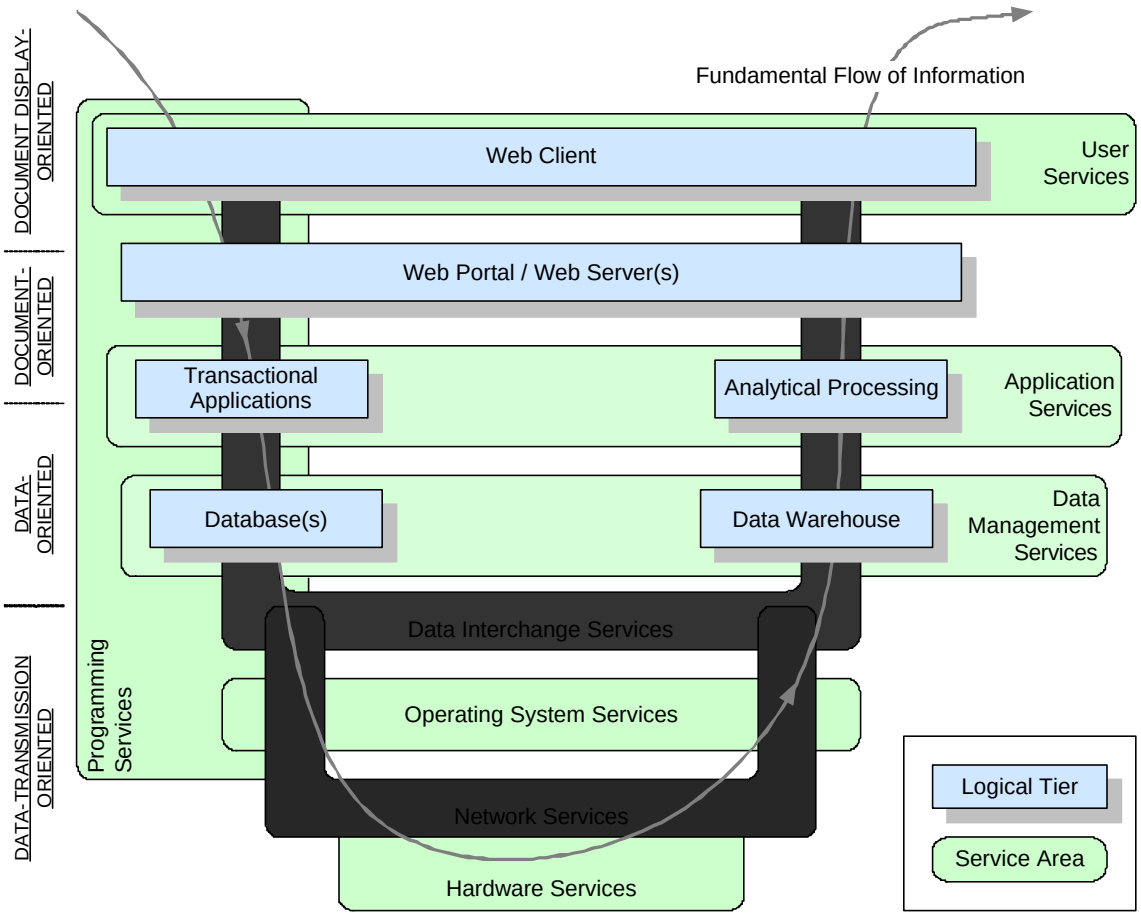

Figure 2. Key TRM service areas (user, application, data management, operating system, hardware) map to the logical tiers of a modern information system. The Data Interchange service area supports the flow of information into and out of the overall system. Network services are the "plumbing" for that flow. Programming services support design-time customization in all the other areas.

The remaining five service areas have some degree of crosscutting from this perspective. The data interchange service area crosscuts the upper software layers; it covers the channel through the layers that supports information flow. Similarly, network services include both operating system and hardware components. Programming services crosscut all the non-hardware service areas and are mainly distinguished as design-time services rather than run-time services. The security and systems management areas have already been defined as crosscutting all the other areas and have been omitted from Figure .

Partially Crosscutting Service Areas:

- Data Interchange (User, Application, Data Management)
- Network Services (Operating System, Hardware, Data Interchange)
- Programming (User, Application, Data Management, Data Interchange, Operating System, Network – at Design Time)

Fully Crosscutting Service Areas:

- Security
- Systems Management

Another way to view the upper layers of the TRM is with respect to their effect on enterprise information:

- User Services – Capture and display information
- Application Services – Transform and interpret information
- Data Management Services – Store and retrieve information
- Data Interchange Services – Format and move information

Note that neither "application services" nor "programming services" means "reusable components". This can be the meaning given to one or the other of these service areas in other contexts, but the FDA EA perspective is that "reusable components" fill the entire TRM – all service areas. This is a foundational principle for the pursuit of enterprise architecture and standards promotion in the first place.

A key benefit to taking the logical-tier perspective outlined above is that the resulting technology architecture directly supports the application architecture (which in turn supports the business architecture).

3.2 SERVICE AREA CONSTITUENTS

Another dimension to the value of the service areas is the constituency they serve. While all the service areas are generally implemented by and controlled by FDA IT support personnel or developers, and all service areas affect the quality of service provided to end users, each has a different balance of concerned constituents. These are shown in the following table.

Service Area	Primary Constituents
User Services	End Users
Application Services	End Users, Development Teams
Programming Services	Development Teams
Data Management Services	Development Teams, IT Support Personnel
Data Interchange Services	Development Teams, IT Support Personnel
Network Services	IT Support Personnel
Operating Systems	IT Support Personnel
Hardware Platforms	IT Support Personnel

Security	IT Support Personnel, End Users
Systems Management	IT Support Personnel

The variation in constituency by service area implies that the selection of technology standards requires different criteria, different representative personnel, and different granularities of change, rationale, and promotion. Organization support in the form of working groups, approval processes, training, help desk procedures, and overall administration should take these differences into account.

4 SERVICE CATEGORIES

Each of the ten service areas of the C-TRM is divided into multiple service categories. Each service category serves to identify a sub-component of technology tools and/or standards that support and further define the service area. As noted earlier, some tools may reside in multiple service areas due to their varying uses by different service constituents.

In an effort to facilitate center and office application-sharing and common use of tools within the FDA, the CDER service categories reflect the FDA service categories. As the enterprise architecture matures, additional service categories may defined.

The following descriptions have been extracted and updated from the FDA Technical Reference Model, Version 1.1. CDER-specific categories will be highlighted as they are identified and added.

4.1 USER SERVICES

User services are the means by which people interact with applications. User services involve displaying information on screen or in print, accepting user input, and guiding the user through an interactive workflow. User services include window management, dialog support, multimedia specifications, web page display, and complete end-user applications for routine office automation.

Service Category	Description
Assistive Interfaces	An interface that helps make electronic and information technology accessible to people with disabilities.

Service Category	Description
Imaging and Multimedia	Standard formats for representing audiovisual information. Standards for the exchange of raster graphics, vector graphics, video images, and sound. Tools and libraries for the capture, editing, transmission, or playback of multimedia information. End user products or programming libraries for the creation, processing, communication, decoding, and display of static and dynamic images.
Office Automation	Tools that address the common needs of all organizations and are almost exclusively COTS products. Core applications include word processing, spreadsheet, presentation, contact management, e-mail clients, personal databases, etc.
Web-Based Interfaces	User interface applications that provides a thin-client layer that navigates a web of interconnected documents on the World Wide Web (WWW). Standards that define the format of documents displayed over the web.
Windowing Systems	Software services for displaying graphical user interfaces as windows, dialogs, controls, etc. Software libraries for creating GUI screens and responding to user input. Standards for representing GUI descriptions.

4.2 APPLICATION SERVICES

Application services are utilities, software libraries, components, or whole applications that support the interpretation and transformation of data from a raw form into a structured and possibly summarized form. Application services are often the most complex part of system development and maintenance. They embody the domain-specific knowledge of an overall application or enable general capabilities that apply to a domain-specific context. Application services directly support business processes, and they satisfy the business- or domain-level requirements for a system. Application services in general terms support information analysis and reporting, business rule enforcement, document I/O, and workflow automation. Note that many but not all software libraries, frameworks, and components fall under this service area. Others support user interfaces, data storage and interchange, or basic network communications. Large COTS software packages, however, generally do fit one of the application service categories.

Service Category	Description
Analytical Processing	Software services or complete applications that support online analytical processing (OLAP), business intelligence, statistical summaries, data mining, etc.

Service Category	Description
Business Administration	Full off-the-shelf applications or sizeable component building blocks for typical business administration needs: financial management, human resources management, customer relations, etc. General administrative management information systems (not FDA domain-specific applications).
Document Scanning	Software and hardware products that scan documents from paper form to digital form. Optical character recognition products and services. Standard protocols or formats for the transmission and storage of scanned information.
Report Generation	Both ad-hoc query and canned report functions: • End-user interfaces for performing ad-hoc queries and reports against a database or data warehouse. These tools allow an analyst to get a business rather than engineering view of data. • Development tools or end-user utilities that support the generation of fixed, predefined reports.
Search and Indexing Engines	Systems that offer the capability to perform search and index over multiple repositories of data (e.g. relational databases and HTML content).
Workflow Automation	Tools that support the automation of business processes. In general, workflow allows the business to define the business processes in terms of the information systems and personnel. As steps in the business process are completed, the work still to be done is automatically determined and routed to the correct personnel or system.

4.3 PROGRAMMING SERVICES

Programming services support the development of applications. They include languages, tools, and methodologies that apply at information systems design-time (as opposed to run-time). Programming services support not just design and implementation, but the entire software development lifecycle – all the disciplines of software engineering from business modeling and requirements engineering to QA and final deployment. Programming services support a variety of activities from the minimally skilled creation of mostly static web sites to low-level coding in Java or SQL. Note that programming services do not include software libraries, frameworks, or components except those few that support the programming effort itself, such as process frameworks and tool automation APIs.

Service Category	Description
Analysis and Design	Tools to capture the results of analysis and design activities. Typical tools support a means to produce a visual representation of a given analysis and/or design model. Standards for analysis and design notation.
Business Modeling	[DHHS] Tools to capture the results of business modeling activities. Typical tools support a means to produce a visual representation of a given business model. Standard notations for business model diagrams.
Change Management	Tools that provide a change request management (CRM) system for the dynamic and interactive nature of software development. With CRM, team members manage several types of change activity associated with software development, including enhancement requests, defect reports, and documentation modifications.
Configuration Management	Tools that control changes to and maintain the integrity of project artifacts. An organization's configuration management (CM) system holds key information about its product development, promotion, deployment and maintenance processes, and retains the asset base of potentially re-usable artifacts resulting from the execution of these processes. Standards defining the minimum capabilities of CM tools.
Data Modeling	Tools to capture the results of data modeling activities. Typical tools support a means to produce a visual representation of a given data model (e.g. logical, physical). Standards for data modeling notation. Utilities for physical data modeling, query optimization, query profiling, etc.
Enterprise Architecture Modeling	Tools to capture the perspectives of an enterprise architecture from multiple perspectives including: Business, Data, Application, Technology, Security.
Online Content Management	Applications to create, manage, personalize and deliver static and dynamic content across the Web (Internet, Extranet and Intranet). Tools for authoring or reviewing XML documents, especially schema or DTDs. Online help authoring tools.
Programming Languages and Environments	Programming languages and supporting development environments. Standards that define programming language syntax and semantics. Tools that enable the rapid development of application software. Integrated development environments (IDEs) that generally provide a framework to which additional software engineering tools can be easily added.
Project Management	Tools that enable the planning, staffing, execution, and monitoring of projects. Standards for how project management is accomplished.

Service Category	Description
Requirements Management	Tools that help teams organize, prioritize, track, and control the changing requirements of a system or application. Standard notations and methodologies for capturing and representing requirements.
Software Engineering Process	Methodologies that show how software engineering best practices can be applied, and how tools can automate a software engineering process.
Testing	Tools that enable evaluation and assessment of the quality of an application or system.

4.4 DATA MANAGEMENT

Data management refers to the storage and retrieval of structured (typically relational, sometimes object-oriented) data. Data management services generally provide for centralized management of data shared by multiple applications. These services support the definition, storage, and retrieval of data elements and enforce basic data integrity rules, generally via transactions. Data management services include data dictionary and directory services, database management systems, and data warehouses.

Service Category	Description
Data Warehousing	Systems that store large quantities of historical data for primarily non-transactional reporting purposes. Standards defining the operation of data warehouses. Standards or tools for managing metadata.
Database Management	Tools that store, organize, and manage data for applications. There are several organizational levels at which data is stored and many approaches for organizing it, including hierarchical, relational, and object-oriented. Typical basic database services include: (1) An API for applications to store and retrieve data, (2) Some type of query language (usually the Structured Query Language or SQL) to identify the pertinent data, (3) Tools to manage data sources. In addition to the basic services, larger databases also usually include: (1) Support for a high volume of requests, (2) Transaction support to ensure data integrity, (3) Clustering support to ensure database scalability and reliability.
Document Management	Services that allow for easy location and retrieval of documents as well as an established process for creating and updating documents. Standard general-purpose document storage formats.

4.5 DATA INTERCHANGE

Data interchange services provide specialized support for the exchange of information, including the format and semantics of data entities communicated between applications on potentially

different platforms. Data interchange includes both distributed communication within the tiers of a single application and distributed communication between applications.

Service Category	Description
Application Integration	Services for integrating separate applications – message queuing, distributed component models, web services. Such services are often asynchronous and offer delivery guarantees and transaction support for the delivery of information from one application to another by means above the level of shared data.
Application Servers	Systems or components that provide support for application services in an N-tier architectural model. These services include: transaction management, persistence, security mechanisms, dynamic web page generation, object brokers, and component frameworks. Also, technology standards for the operation of these systems.
Data Access	Relatively low level software tools, libraries, and standards that enable the retrieval and storage of data to and from databases, file servers, or document stores by applications. O/R mapping tools that convert relational database records to and from object-oriented applications. Protocols for communication with database driver software. XML or EDI parsing and generation libraries.
Data Element Standardization	Standards that apply to the domain-specific formulation of data element representations and meaning as shared among people and machines. Common vocabularies, thesauruses, domain-specific data formats.
Data Extraction, Transformation, and Loading	Utilities for extraction, cleansing, transformation and loading of data from OLTP databases to a data warehouse. Utilities or standards for data replication or clustered databases.
E-Mail Transfer	Services that support the interchange of E-mail between users within the organization and across organizations. Widely accepted industry standards and products allow for seamless interchange between platforms. Areas such as E-mail transport, servers, and gateways are addressed by this service category. (Note: end user e-mail clients are categorized as "office automation.")
Legacy Integration	Transitional mechanisms that support the integration of legacy applications into the FDA Enterprise Architecture. For example, mechanisms that allow 2-Tier applications to be incorporated into an N-Tier architectural environment.
Web Portals	Environments that support a uniform web-based front-end to the myriad of FDA internal and external applications.

Service Category	Description
Web Servers	Server components that primarily communicate web pages to end users.

4.6 NETWORK SERVICES

Network services provide connectivity and basic services to foster communications across workgroups and sites. These services comprise the network infrastructure that supports distributed data access and interoperability in a heterogeneous environment. Components of this category include network hardware, data communications, directory services, transparent file access/transfer, and remote or wireless network access.

Service Category	Description
Cabling & Physical Media Access	Standards and supporting infrastructure that enable access to LAN/WAN system resources. Standards and supporting infrastructure for the physical integration of network components – cabling, connection, etc. Standards governing the electronic or optical operation of physical communications between network nodes. The physical communications layer of the network.
Hubs, Concentrators, and Switches	Hardware systems that control the operations of a single network, including switches, hubs, bridges, repeaters, etc.
Naming and Directory Services	Network services that identify all resources on a network and make them accessible to users and applications. Resources include e-mail addresses, computers, and peripheral devices such as printers. Utilities to support the sharing of resources across heterogeneous platforms, e.g. file and print sharing across operating systems. Domain naming and control services that translate domain names into IP addresses and route network communications. Standards that govern how these products function.
Network Address Management	Lower level software services for assigning network addresses to network-connected equipment. Policies and standards for how address management is done at the FDA.
Remote Access Services	Services that offer dial-up, wireless, or other types of remote access to the FDA internal network.
Routing Services	Products that govern traffic between different network segments – to and from the internet or across a wide area network - routers, gateways, VPN appliances, hardware firewalls, etc. Standards, policies, and protocols that govern the operation of these products.

Service Category	Description
Transport Protocols	Network transport and link layer services – the software protocols that support reliable data transmission across a heterogeneous network of computers. Higher level protocols for file transfer.

4.7 OPERATING SYSTEMS

Operating system services provide the software environment and base interfaces within all computing devices to interface with the hardware. An operating system manages machine processing and I/O resources as they are shared by multiple applications running on that machine.

Service Category	Description
Desktop Workstation Operating Systems	Standard operating environments for the management of desktop workstation resources (e.g. memory, CPU, processes, disk utilization, etc.).
Server Operating Systems	Standard operating environments for the management of server-based resources (e.g. memory, CPU, processes, disk utilization, etc.).

4.8 HARDWARE PLATFORMS

The hardware platform service area provides the physical layer for computational resources. Hardware platforms are workstations, servers, storage devices, mobile devices, printers, and other electronic peripherals that make information processing physically possible.

Service Category	Description
Desktop Workstation Platforms	Standard hardware configurations for end users. These configurations encompass the needs for all locations including data processing centers, field offices, development centers, etc.
Mobile Platforms	Standard hardware configurations to support mobile users. This shall include mobile and wireless devices. Standards defining wireless access to information.
Power Management Technologies	Technologies that ensure power and proper processing in the case of power failure. To ensure data integrity and consistency, policies and support must be in place to store data in non-volatile memory in case of power failure.
Printers	Printing hardware that produces paper output from electronic information. Associated standards for how documents are sent to printers.

Service Category	Description
Server Platforms	Standard hardware configurations to support web, application and database services. This includes network devices, web/application servers, file/print servers, database servers, load balancing hardware, etc.
Storage Technologies	Standard hardware configurations to support highly available and scalable online and off-line storage systems (e.g. disk storage arrays, tape storage). This service area also includes the selection of appropriate Redundant Array of Independent (or Inexpensive) Disks (RAID) strategies.

4.9 SECURITY (CROSSCUTTING)

Security services ensure secure distribution and integrity of information and protect the computing infrastructure from unauthorized access at all levels. The FDA enterprise architecture defines an accepted set of security services in order to ensure the integrity of mission critical information.

Service Category	Description
Access Control	Products and protocols for ensuring correctly authorized access to FDA network resources. Policies and procedures that cover physical access to FDA offices, labs, computer centers, and IT resources in general. Products and standards for remote access, wireless access, etc.
Authentication	Products (hardware and software) that support accurate identification and authentication of FDA users. Standard authentication protocols for software systems. Significant aspects of this category include PKI and single-sign-on technologies.
Electronic Signatures	Technologies that allow documents to be electronically signed for auditing and non-repudiation purposes.
Encryption	Standard software-based or hardware-based mechanisms for certified secure communications over a network. Products and standards that encrypt information stored in user files.
Internet Firewalls	Standards and supporting infrastructure to prevent unauthorized access to FDA private networks.
Intrusion Detection	Systems that detect and prevent unauthorized access to the FDA network.
Security Scanning	Applications that scan network systems and ports to identify potential security vulnerabilities.

Service Category	Description
Virus Protection	Systems that prevent data containing known computer viruses to be placed into the FDA system environment. These systems run on either end user workstations or on file or e-mail servers.

4.10 SYSTEMS MANAGEMENT (CROSSCUTTING)

Systems management includes mechanisms to monitor and control the operation of individual applications, databases, systems, platforms, and networks, often remotely. Systems management utilities control user interaction with these components at all levels.

Service Category	Description
Asset Inventory Management	Software and hardware (e.g. barcode) tools to collect (automatically or manually) the inventory of IT assets (e.g. hardware products, software products, license information) within the FDA organization. Capacity management tools that support the forecasting of required system resources to support future FDA demands.
Database Administration	Centralized tools for administering enterprise databases. Tools to control user access, storage requirements, data backups, replication, etc. (This category does not include schema definition or data manipulation.)
Hard Disk Management	Software applications that support hard drive partitioning, dual boot capabilities, disk fragmentation, formatting, duplication, etc. Utilities for creating images of workstation hard drives for rapid and repeatable configuration of end user workstations.
File Compression	Standards and software/hardware tools for compressing user files or entire hard drives.
Network Management	Tools that enable the centralized management of FDA distributed systems.
Performance Management	Tools that support the optimization of network traffic, hardware resource usage, application or software system performance, and response times via tuning, monitoring, and capacity planning tools.
Remote Control	Tools and policies that support the administrative control of remote devices.
Service Desk Software	Software tools that enable problem change and call management for deployed FDA applications and their supporting infrastructure.
Software Distribution	Tools and policies that support the distribution of software to targeted devices.

Service Category	Description
Storage Management	Tools and policies that support the backup, restore, archival and retrieval of mission critical application and data resources.